

Amendments to the Claims

The following listing of claims replaces all prior versions of listing of claims in the application:

1. (Currently canceled)
2. – 3. (Previously canceled)
4. (Currently canceled)
6. (Currently canceled)
7. – 8. (Previously cancelled)
9. (Currently canceled)
10. (Currently canceled)
11. (New) A method of providing isolated orthorhombic crystalline 4-[6-acetyl-3-[3-(4-acetyl-3-hydroxy-2-propylphenylthio)propoxy]-2-propylphenoxy]butyric acid, which orthorhombic crystalline form (i) is substantially free of monoclinic crystalline forms as evidenced by powder x-ray diffraction (PXRD) analysis showing the absence of doublet peaks between about 11.5 and 16 (2-Theta scale), and (ii) exhibits at least about twice the solubility of a monoclinic crystalline form at 30 °C in aqueous ethanol, comprising:
 - (a) dissolving 4-[6-acetyl-3-[3-(4-acetyl-3-hydroxy-2-propylphenylthio)propoxy]-2-propylphenoxy]butyric acid in 5 to 10 parts by weight of ethanol and 1 to 10 parts of water, agitating the resulting suspension at 20 – 25 °C for 15 – 60 minutes and then cooling to 5 – 10 °C for an additional period of 1 – 4 hours;
 - (b) adding to this suspension 5 to 15 parts of water and agitating the mixture at 5 – 10 °C for an additional 1 – 4 hours; and
 - (c) isolating orthorhombic crystals of 4-[6-acetyl-3-[3-(4-acetyl-3-hydroxy-2-

propylphenylthio)propoxy]-2-propylphenoxy]butyric acid, which are substantially free of monoclinic crystalline forms.

12. (New) A method of providing isolated orthorhombic crystalline 4-[6-acetyl-3-[3-(4-acetyl-3-hydroxy-2-propylphenylthio)propoxy]-2-propylphenoxy]butyric acid, which orthorhombic crystalline form (i) is substantially free of monoclinic crystalline forms as evidenced by powder x-ray diffraction (PXRD) analysis showing the absence of doublet peaks between about 11.5 and 16 (2-Theta scale), and (ii) exhibits at least about twice the solubility of a monoclinic crystalline form at 30 °C in aqueous ethanol, comprising:

(a) dissolving 4-[6-acetyl-3-[3-(4-acetyl-3-hydroxy-2-propylphenylthio)propoxy]-2-propylphenoxy]butyric acid in 5 to 7 parts by weight of ethanol at 30 – 40 °C and adding 1 – 2 parts of water, cooling the mixture to 10 – 15 °C over 2 – 3 hours and then cooling to 5 – 10 °C for an additional period of 1 – 4 hours;

(b) adding to this suspension 5 – 15 parts of water and agitating the mixture at 5 – 10 °C for an additional 1 – 4 hours; and

(c) isolating orthorhombic crystals of 4-[6-acetyl-3-[3-(4-acetyl-3-hydroxy-2-propylphenylthio)propoxy]-2-propylphenoxy]butyric acid, which are substantially free of monoclinic crystalline forms.

13. (New) A method of isolated orthorhombic crystalline 4-[6-acetyl-3-[3-(4-acetyl-3-hydroxy-2-propylphenylthio)propoxy]-2-propylphenoxy]butyric acid, which orthorhombic crystalline form is substantially free of monoclinic crystalline forms, comprising:

(a) dissolving 4-[6-acetyl-3-[3-(4-acetyl-3-hydroxy-2-propylphenylthio)propoxy]-2-propylphenoxy]butyric acid in ethanol;

(b) adding water and cooling the resulting mixture first to about 10 – 15 °C and second to about 5 – 10 °C,

(c) adding more water and agitating the resulting mixture at about 5 – 10 °C, and

(d) isolating the orthorhombic crystals of 4-[6-acetyl-3-[3-(4-acetyl-3-hydroxy-2-propylphenylthio)propoxy]-2-propylphenoxy]butyric acid, which are substantially free of monoclinic crystalline forms.

14. (New) A method of recrystallizing 4-[6-acetyl-3-[3-(4-acetyl-3-hydroxy-2-propylphenylthio)propoxy]-2-propylphenoxy]butyric acid, comprising:
- (a) dissolving 4-[6-acetyl-3-[3-(4-acetyl-3-hydroxy-2-propylphenylthio)propoxy]-2-propylphenoxy]butyric acid in 5 to 10 parts by weight of ethanol at about 25 – 40 °C;
 - (b) adding 1 – 10 parts of water and agitating at 20-25 °C for about 15 – 60 minutes;
 - (c) cooling to about 5-10 °C for a period of 1 - 4 hours;
 - (d) adding 5 – 15 parts of water and agitating at about 5 – 10 °C for a period of 1 – 4 hours; and
 - (e) isolating orthorhombic crystals of 4-[6-acetyl-3-[3-(4-acetyl-3-hydroxy-2-propylphenylthio)propoxy]-2-propylphenoxy]butyric acid, which are substantially free of monoclinic crystalline forms.
15. (New) The method of claim 14 in which the cooling of step (c) is carried out for a period of 2 – 3 hours.
16. (New) The method of claim 14 in which the agitating of step (d) is carried out for a period of 1.5 – 2 hours.
17. (New) A method of recrystallizing 4-[6-acetyl-3-[3-(4-acetyl-3-hydroxy-2-propylphenylthio)propoxy]-2-propylphenoxy]butyric acid, comprising:
- a) dissolving 4-[6-acetyl-3-[3-(4-acetyl-3-hydroxy-2-propylphenylthio)propoxy]-2-propylphenoxy]butyric acid in 5 to 10 parts by weight of ethanol at about 25 – 40 °C;
 - b) adding 1 – 10 parts of water;
 - c) agitating at about 20-25 °C for a period of about 15 – 60 minutes;
 - d) agitating at about 5-10 °C for a period of about 1 - 4 hours;
 - e) adding 5 – 15 parts of water;
 - f) agitating at about 5 – 10 °C for a period of about 1 – 4 hours; and
 - g) isolating orthorhombic crystals of 4-[6-acetyl-3-[3-(4-acetyl-3-hydroxy-2-propylphenylthio)propoxy]-2-propylphenoxy]butyric acid, which are substantially free of monoclinic crystalline forms.

18. (New) A method of preparing a pharmaceutically acceptable tablet or capsule containing isolated orthorhombic crystalline 4-[6-acetyl-3-[3-(4-acetyl-3-hydroxy-2-propylphenylthio)propoxy]-2-propylphenoxy]butyric acid, which orthorhombic crystalline form is substantially free of monoclinic crystalline forms, comprising:

a) combining pharmaceutically acceptable components of a tablet or capsule, including isolated orthorhombic crystalline 4-[6-acetyl-3-[3-(4-acetyl-3-hydroxy-2-propylphenylthio)propoxy]-2-propylphenoxy]butyric acid, which orthorhombic crystalline form is substantially free of monoclinic crystalline forms, to provide a mixture; and

b) compressing the mixture into a tablet or filling a capsule with the mixture.

19. (New) The method of claim 18 which further comprises a wet granulation step or a dry granulation step prior to the compression step in the case of a tablet.